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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,989	02/08/2002	Randy Dinkins	028750-219	9928

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EXAMINER	
KUBELIK, ANNE R	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,989	DINKINS ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *8,9,15-27,32 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-14 and 28-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 May 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-33 are pending.

2. This application contains claims 8-9, 15-27 and 32-33 drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims and deletion of nonelected subjected matter from the examined claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

4. Claims 1-7, 10-14 and 28-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 2 July 2004. Applicant's arguments filed 3 January 2005 have been fully considered but they are not persuasive.

Neither the instant specification nor the originally filed claims appear to provide support for the phrase "wherein the exogenous gene does not cross-hybridize with an homologous gene of the plant cell" in claims 1, 10 and 28. Thus, such a phrase constitutes NEW MATTER.

Applicant urges that the phrase is supported by the transformation of MinD/MinE of Arabidopsis into tobacco on pg 7 and 14 and the showing that AtMinE1 did not cross-hybridize to the tobacco homologues on pg 16 (response pg 10).

This is not found persuasive. Pg 7, lines 19-25 of the specification is drawn to a definition of "derived from", and does not discuss the exogenous gene not cross-hybridizing with an homologous gene of the plant cell. Pg 14, lines 10-27 of the specification discuss transformation of tobacco with the Arabidopsis MinD or MinE genes operatively linked to a promoter, with the statement that transformation with multiple copies of the gene might result in silencing of the gene's activity; it does not discuss the exogenous gene not cross-hybridizing with an homologous gene of the plant cell. Pg 16, lines 5-6, are drawn to use of AtMinE1, while the claims are drawn to vectors encoding a protein with the same functional activity of the Arabidopsis MinD gene. Thus, there is no support for the phrase "wherein the exogenous gene does not cross-hybridize with an homologous gene of the plant cell" in claims 1, 10 and 28. T

5. Claims 1-7, 10-14 and 28-31 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vector encoding the *Arabidopsis* MinD protein, plants and cells transformed with it and a method of using it to produce a plant with one or few chloroplasts, does not reasonably provide enablement for vectors comprising a gene encoding a protein with the same functional activity as the *Arabidopsis* MinD protein or having a "significant amount of homology to" the *Arabidopsis* MinD protein, plants and cells transformed with them and a method of using them to produce a plant with one or few chloroplasts. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these

claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 2 July 2004. Applicant's arguments filed 3 January 2005 have been fully considered but they are not persuasive.

Applicant urges that the skilled artisan would be able to identify genes that encode proteins with the same functional activity as the Arabidopsis MinD gene without undue experimentation, and that such genes are taught by the specification (response pg 12).

This is not found persuasive because the specification only teaches one plant MinD, from Arabidopsis, a possible Chlorella sequence, and two bacterial sequences, one of which is only a possible sequence. MinD sequences are not taught within the full scope of the claims.

Applicant urges that the specification discloses homologues and methods of their identification on pg 7-9, defines functional activity as resulting the production of fewer and larger chloroplasts on pg 13, and provides guidance for determining if a proteins has that function on pg 14-15 (response pg 12).

This is not found persuasive. Pg 7-9 of the specification is merely drawn to a discussion of what percent identity a homologue might have, alignment programs, and general guidance for hybridization. Pg 13 teaches a bacterial MinD gene, but pg14-15 merely teaches transformation; sequences of homologous genes are not taught. .

Applicant urges that Figure 1 presents an alignment of several MinD homologs and the skilled artisan could use the information on conserved amino acids to determine amino acid substitutions (response pg 12-13).

This is not found persuasive because the making of such substitutions to produce a functional protein is not predictable. Hill et al (1998, Biochem. Biophys. Res. Comm. 244:573-

577) teach that three presumably catalytic histidines that are maintained in the same position ADP-glucose pyrophosphorylase across 11 bacterial and plant species (abstract and pg 573, right column, paragraph 3); one would expect that an amino that is so strongly conserved would tolerate either no substitutions or only conservative substations with other basic amino acids. The substitution of one of those histidines with the conservative amino acid arginine drastically reduced enzyme activity; however, substitution with the nonconservative amino acid glutamine, had little effect on enzyme activity (see Table 1). Lazar et al (1988, Mol. Cell. Biol. 8:1247-1252) showed that the "conservative" substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor alpha while "nonconservative" substitutions with alanine or asparagine had no effect (abstract). Thus, amino acid substitution is unpredictable.

Applicant urges that the MinD database is merely an example of what was known in the art, and sufficient information was available to one of skill in the art at the time of filing, and that at the time of filing one of skill in the art routinely compared amino acid sequences to identify conserved amino acids and the MinD database is a collection is such analyses (response pg 13).

This is not found persuasive because the specification does not teach the sequences of homologous genes within the full scope of the claims; for example, no other plant MinD gene is taught. Applicant also gives no indication of what MinD sequences were known at the time of filing.

6. Claims 1-7, 10-14 and 28-31 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in

the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 2 July 2004. Applicant's arguments filed 3 January 2005 have been fully considered but they are not persuasive.

Applicant urges that the subject matter does not need to be described literally (response pg 10-11).

This is not found persuasive because a description of MinD genes within the full scope of the claims is required. While this does not mean that each and every possible MinD sequence must be described, it does mean, for example, that more than one plant Min D sequence is required to describe a representative sample of plant MinD genes.

Applicant urges that the vectors, methods and plants would be easily determined by the skilled artisan through what was known at the time the invention was filed, and the NCBI database provided the skilled artisan with the information needed to know which DNA molecule was are encompassed by the claimed invention or which sequences encode a derivative of the MinD protein; a listing of each and every sequence encompassed by the claims us not necessary (response pg 11).

This is not found persuasive because the specification does not describe the sequences of MinD genes within the full scope of the claims. While Applicant mentions the NCBI database, Applicant does not indicate what MinD sequences were known at the time of filing, other than the two known and two possible sequences listed in Figure 1. No sequences that encode a derivative of the MinD protein are described in the specification, and Applicant does not point to other sources of descriptions of these sequences.

7. Claims 1-7, 10-14 and 28-31 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the reasons of record as set forth in the Office action mailed 2 July 2004. Applicant's arguments filed 3 January 2005 have been fully considered but they are not persuasive.

Claims 1, 5-7, 10-13 and 28-31 are indefinite in their recitation of "exogenous". It is not clear to what the gene is exogenous - the vector? *Arabidopsis*? a randomly chosen plant?

Applicant urges that an exogenous gene is one that is produced outside of an organism, and that a skilled artisan could determine that the gene is exogenous to tobacco from reviewing the specification (response pg 14).

This is not found persuasive because whether a particular vector is encompassed by the claims would depend upon the intended use of the vector - a vector comprising the Arabidopsis MinD gene would be encompassed if one intended to use it to transform tobacco, but not if one intended to use it to transform Arabidopsis, even though the vector itself has not changed. The phrase is indefinite because a product must be encompassed by or excluded from the claim under all circumstances.

Claims 1, 10 and 28 are indefinite in their recitation of "a protein with the same functional activity as a protein encoded by the *Arabidopsis thaliana* ... *MinD* gene". It is unclear which protein encoded by the *MinD* gene is being referred to. Additionally, it is not

clear what the exact function of the *Arabidopsis* MinD protein - what proteins does it interact with, what is its exact enzymatic activity?

Applicant urges that the function of the MinD protein is clearly defined on pg 13 of the specification as causing "the production of fewer and larger chloroplasts", that the structure of the MinD gene is known in the art, and that any protein that has that function would qualify, whether or not it is a MinD gene (response pg 14).

This is not found persuasive. Applicant's response makes the issue less clear, rather than more. The function of the MinD gene, in terms of exact enzymatic activity, is not defined.

Claims 1, 10 and 28 are indefinite in their recitation of "wherein the exogenous gene does not cross-hybridize with an homologous gene of the plant cell". It is unclear what level of hybridization this is, as all nucleic acids will "cross-hybridize" with all other nucleic acids under at least some conditions.

Applicant urges that cross-hybridization details are described in the specification at pg 8-9, and thus a skilled artisan, using that and what is known in the art would appreciate the meaning of the phrase (response pg 14-15).

This is not found persuasive. The hybridization conditions listed are only non-limiting examples and the specification specifically indicates that. Applicant gives no indication as to what was known in the art. Pg 24-25 do not teach which hybridization conditions were used.

Claims 5, 7, 11, 13, 29 and 31 are indefinite in their recitation of "significant amount of homology to a gene from of Arabidopsis thaliana". It is unclear what gene the exogenous gene has homology to and it is unclear what level of homology is "significant".

Applicant urges that degrees of homology are discussed on pg 8 of the specification, and exemplified in the examples (response pg 15).

This is not found persuasive. The examples exemplify only 100% identity. The degrees of homology listed are only non-limiting examples and the specification specifically indicates that. Where does the specification define what level of homology is "significant"?

Claim 30 lacks antecedent basis for the limitation "The vector according to Claim 30" as claim 30 is drawn to a method.

Applicant urges that claim 30 is amended (response pg 15).

This is not found persuasive because it is not so amended.

Claim Rejections - 35 USC § 102

8. Claims 1-7, 10-13 and 28-31 remain rejected under 35 U.S.C. 102(a) as being anticipated by Colletti et al (2000, Curr. Biol. 10:507-516). The rejection is repeated for the reasons of record as set forth in the Office action mailed 2 July 2004. Applicant's arguments filed 3 January 2005 have been fully considered but they are not persuasive.

Applicant urges that the Colletti s vectors are expressed in an Arabidopsis plant cell and would cross-hybridize with the homologous gene in the plant cell; Colletti does not describe the limitation that the gene is an exogenous gene that does not cross-hybridize with a homologous gene of the plant cell (response pg 16).

This is not found persuasive because the recitation "wherein the exogenous gene does not cross-hybridize with an homologous gene of the plant cell" for the vector is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural

difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963).

The method of claim 28 does not require that the exogenous gene not cross-hybridize with a plant cell in the plant into which the vector is transformed; it only requires that the gene not "cross-hybridize with "a" plant cell - the vector comprises an exogenous gene that encodes a protein that has the same activity as the Arabidopsis MinD gene, affects a plant cell by allowing for expression of only one or few chloroplasts, and wherein the gene does not cross-hybridize with a homologous gene in that plant cell. There is no indication that the plant cell is from the plant into which the vector is transformed in step (b).

It is noted that the vector of Colletti et al and the vector taught on pg 20, lines 7-26 of the instant specification both comprise the Arabidopsis MinD coding sequence operably linked to the 35S promoter.

9. Claims 1-7, 10-13 and 28-31 remain rejected under 35 U.S.C. 102(a) as being anticipated by Kanamaru et al (2000, Plant Cell Physiol. 41:1119-1128 and GenBank Accession No. AB030278, December 2000). The rejection is repeated for the reasons of record as set forth in the Office action mailed 2 July 2004. Applicant's arguments filed 3 January 2005 have been fully considered but they are not persuasive.

Applicant urges that Kanamaru does not disclose that the exogenous gene that does not cross-hybridize with a homologous gene of the plant cell (response pg 17).

This is not found persuasive because the recitation "wherein the exogenous gene does not cross-hybridize with an homologous gene of the plant cell" for the vector is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963).

The method of claim 28 does not require that the exogenous gene not cross-hybridize with a plant cell in the plant into which the vector is transformed; it only requires that the gene not "cross-hybridize with "a" plant cell - the vector comprises an exogenous gene that encodes a protein that has the same activity as the Arabidopsis MinD gene, affects a plant cell by allowing for expression of only one or few chloroplasts, and wherein the gene does not cross-hybridize with a homologous gene in that plant cell. There is no indication that the plant cell is from the plant into which the vector is transformed in step (b).

10. Claims 1-2 and 5-7 remain rejected under 35 U.S.C. 102(b) as being anticipated by Huang et al (1996, J. Bacteriol. 178:5080-5085). The rejection is repeated for the reasons of record as set forth in the Office action mailed 2 July 2004. Applicant's arguments filed 3 January 2005 have been fully considered but they are not persuasive.

Applicant urges that Huang does not disclose that the exogenous gene that does not cross-hybridize with a homologous gene of the plant cell (response pg 17).

This is not found persuasive because the yeast gene would inherently be exogenous to all plants and would not be identical to any plant gene and thus would not "cross-hybridize" to one.

Applicant urges that the in the instant method the claim limitations related to exogenous genes are necessary to prevent gene silencing; Huang et al do not recite all the elements of the claimed invention because methods disclosed by Huang do not disclose a system of increased efficiency (response pg 16).

This is not found persuasive because the rejection is not applied to any method steps.

Furthermore, the recitation "wherein the exogenous gene does not cross-hybridize with an homologous gene of the plant cell" for the vector is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963).

Conclusion

11. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne R. Kubelik, Ph.D.
February 25, 2005

ANNE KUBELIK, PH.D.
PRIMARY EXAMINER